

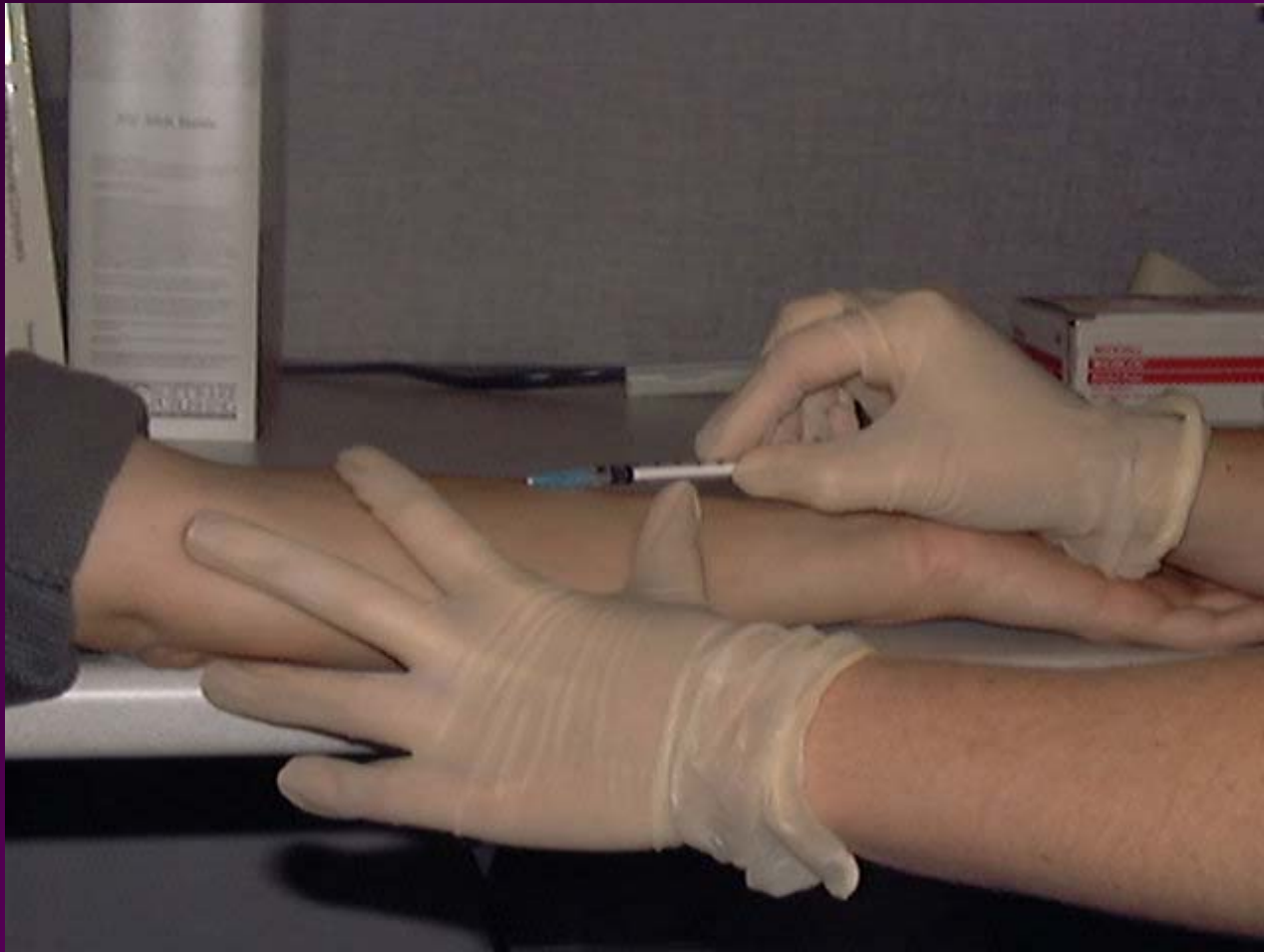


# **Tuberculosis Adherence Partnership Alliance Study**

# Tuberculosis and Latent TB Infection (LTBI)

- There are an estimated 8 million new cases of TB per year globally
- It is estimated that more than one-third of the world's population has LTBI
- LTBI diagnosed through use of tuberculin skin test
- Standard treatment of LTBI consists of 9 months of isoniazid (INH)
- Nature of LTBI treatment is challenging

# Testing for TB Disease and Infection



# Background - 1

- Resurgence of TB in US in the 1990s
- Estimated 10 million individuals with LTBI in US
- Treatment of LTBI is an important strategy in TB control
- Rates of TB in Harlem disproportionately higher than other communities in NYC and US

# Background - 2

- Poor completion rates of self-administered LTBI treatment are a growing concern
- Treatment of LTBI poses unique challenge:
  - Patients have no symptoms
  - Long treatment duration
  - Knowledge & attitudes

# Harlem Hospital



# Overview

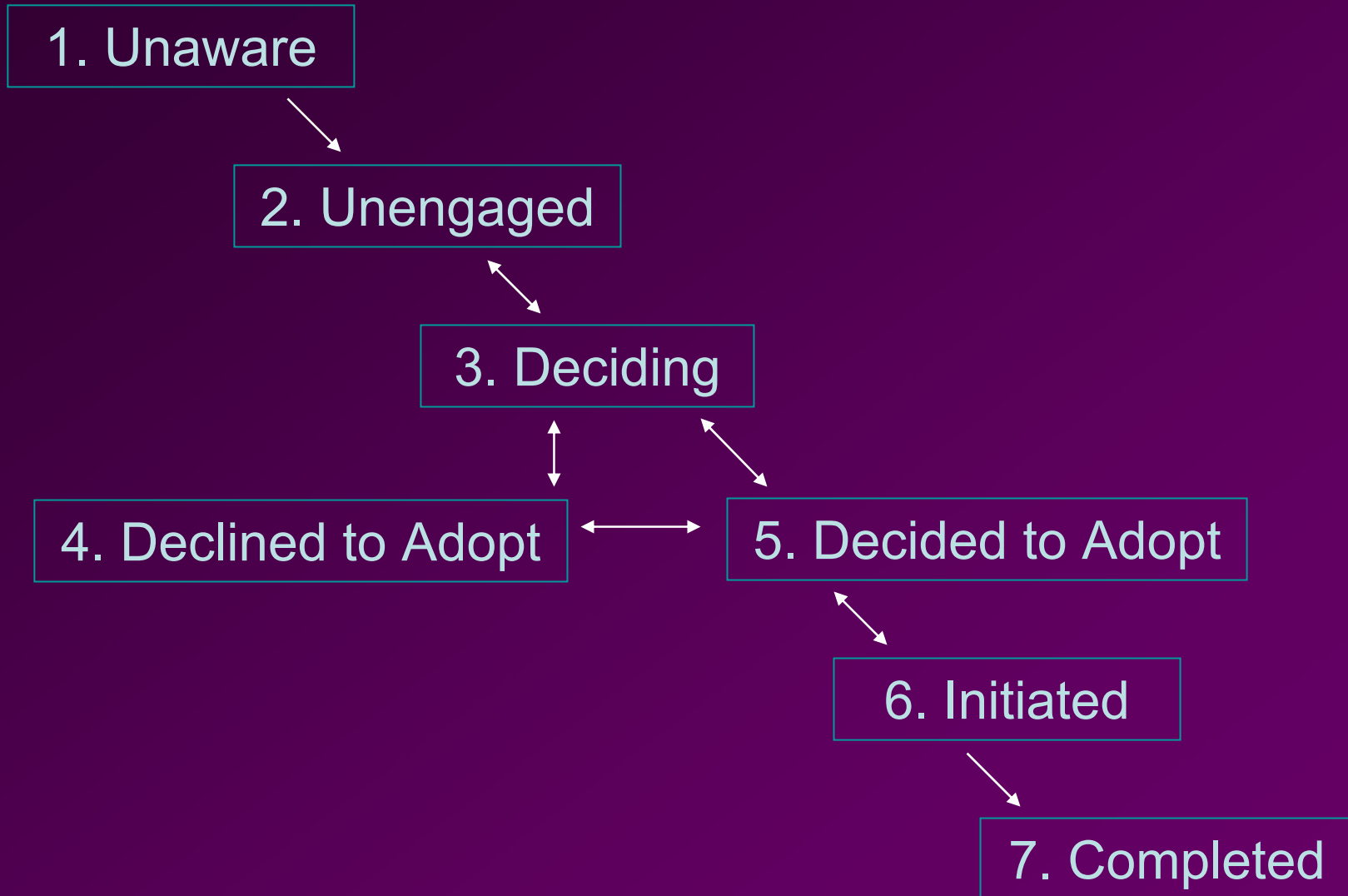
TAPAS is a theory-based peer intervention to promote adherence to and completion of treatment for LTBI

# Theoretical Model

The Precaution Adoption Process Model (PAPM; Weinstein 1998) is a seven stage model of behavioral change that is being used as a tool to assess commitment to initiating and completing LTBI treatment



# PAPM Staging



# PAPM Staging Questionnaire

**1. Do you know why the doctor told you that you should take pills?**

If No, end questionnaire (Stage 1, Unaware)

**2. Would you want to take some time to think about it and talk to others about it before starting the TB pills?**

If Yes, end questionnaire (Stage 2, Unengaged)

**3. Well, do you need more information to think about it?**

If Yes, end questionnaire (Stage 3, Deciding)

**4. Have you decided that you wouldn't take the TB medicines?**

If Yes, end questionnaire (Stage 4, Declined to Adopt)

**5. Would you consider taking the TB medicines to prevent TB?**

If No, end questionnaire (Stage 2, Unengaged)

**6. Are you going to take the TB medicines to prevent TB?**

If No, end questionnaire (Stage 4, Declined to Adopt)

**7. Are you taking them now?**

If Yes, end questionnaire (Stage 6, Initiated)

If No, end questionnaire (Stage 5, Decided to Adopt)

# Study Design And Methodology

## Study Design

Randomized Clinical Trial

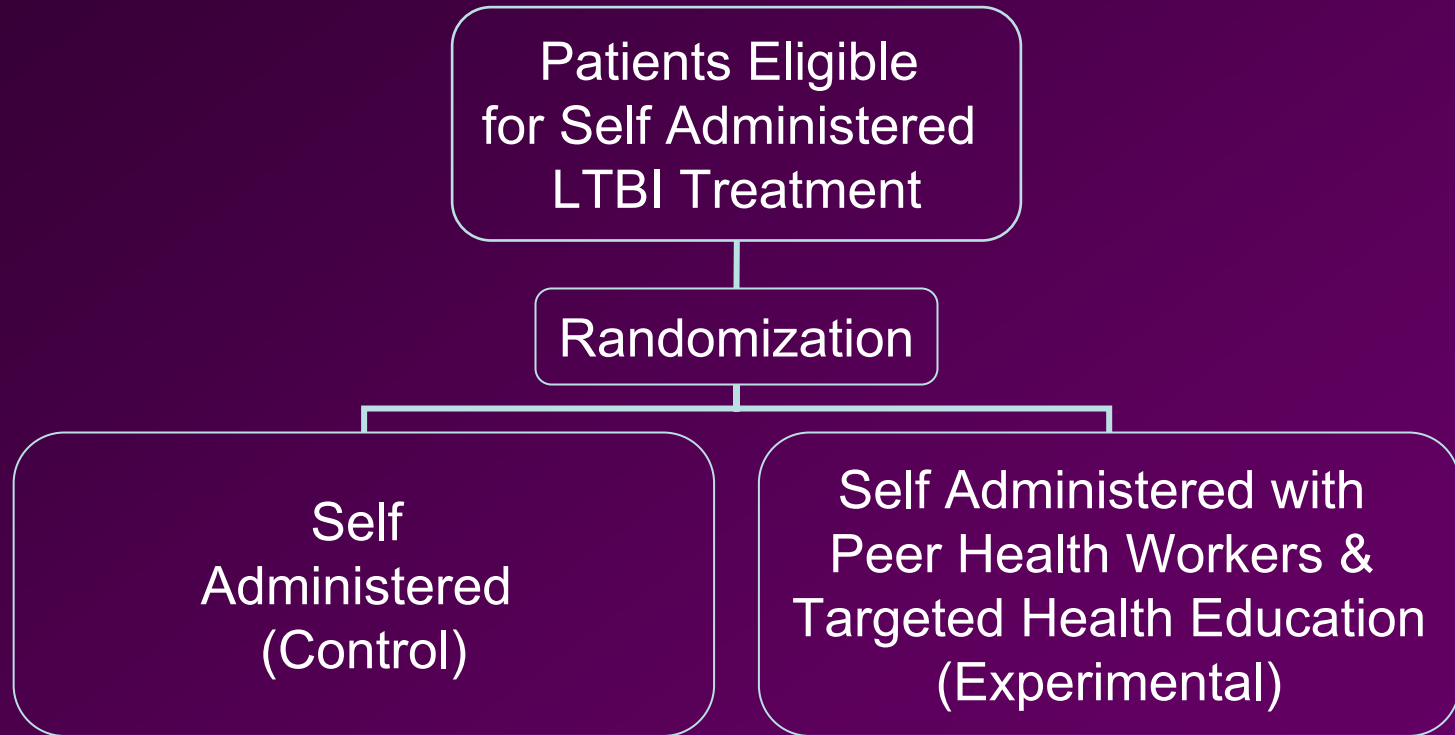
## Setting

Inner city, hospital-based chest clinic

## Eligibility

Adults ( $\geq 18$  years) who are prescribed self-administered treatment for LTBI

# Study Design



# Intervention Components

- Targeted health education
- Peer support



# Targeted Health Education Interventions

Title of Intervention Material	Goals
<b>Stage 1 - Unaware</b>	
Latent Tuberculosis Infection (LTBI) – Huh?	<ul style="list-style-type: none"> <li>•Basic information about LTBI</li> <li>•Help acknowledge risk of TB and its seriousness</li> </ul>
<b>Stage 2 - Unengaged</b>	
What are the Chances?	<ul style="list-style-type: none"> <li>•Influence susceptibility</li> </ul>
Positive TST – The Little Bump on Your Arm + Now What Can You Do to Kill the TB Germ	<ul style="list-style-type: none"> <li>•Specific information about LTBI/TST</li> <li>•See risk of TB through acceptance of diagnosis</li> </ul>
Let's Talk about Treatment to Prevent TB	<ul style="list-style-type: none"> <li>•LTBI information</li> <li>•Benefits of LTBI tx</li> </ul>

# Targeted Health Education Interventions

	Title of Intervention Material	Goals
Stage 3 - Deciding		
	What LTBI Treatment Can Do for Me	<ul style="list-style-type: none"><li>•Risks/Benefits</li><li>•Identify support systems</li><li>•Identify barriers</li></ul>
	Choose Your Own Adventure	<ul style="list-style-type: none"><li>•Provide information to suggest that perceived benefits outweigh barriers</li><li>•Influence feelings of susceptibility</li></ul>
Stage 5 – Decided to adopt		
	Adherence Calendar	<ul style="list-style-type: none"><li>•Resolve barriers to treatment by setting up schedule</li><li>•Incorporate adherence into lifestyle</li></ul>

# Peers & Health Educator





# Peer Worker Qualifications

- Successfully completed TB treatment
- Be members of same community
- Have good communication skills
- Have a caring attitude
- Be committed to TB control

# Peer Worker Activities

- Communicate with patients weekly
- Provide info on importance of treatment
- Encourage medication and visit adherence
- Offer support and empathy
- Provide referrals
- Help navigate system
- Advocate for patient

# Comparison of Interventions

	<u>Exp</u>	<u>Control</u>
monthly clinic visits	✓	✓
use of available resources	✓	✓
discussion of adherence techniques	✓	
monitoring of personal & social situation	✓	
referrals to services	✓	
offer support & encouragement	✓	

# Research Hypotheses

## *Primary Hypothesis:*

- participants assigned to peer-based intervention will achieve higher rates of completion of LTBI treatment than those assigned to control arm

## *Secondary Hypotheses:*

- peer-based intervention will be more cost effective
- socio-demographic and attitudinal factors will be associated with adherence

# Outcome Measures

## Primary Aims

1. to compare completion rates in two groups
2. to compare costs of two models

## Secondary Aims

1. to identify baseline demographic and behavioral factors associated with adherence and completion of therapy
2. to evaluate patient satisfaction, quality of life, and social networks

# Instruments

- Patient Demographics
- PAPM Staging
- Perceived Benefits and Barriers
- TB Knowledge & Attitudes
- Self-Efficacy
- Adherence assessment

# Measures of Adherence

- Participant 3-day self-report
  - Interview
  - ACASI with a touch screen
- Provider assessment
- Adjusted MEMS cap data

# ACASI

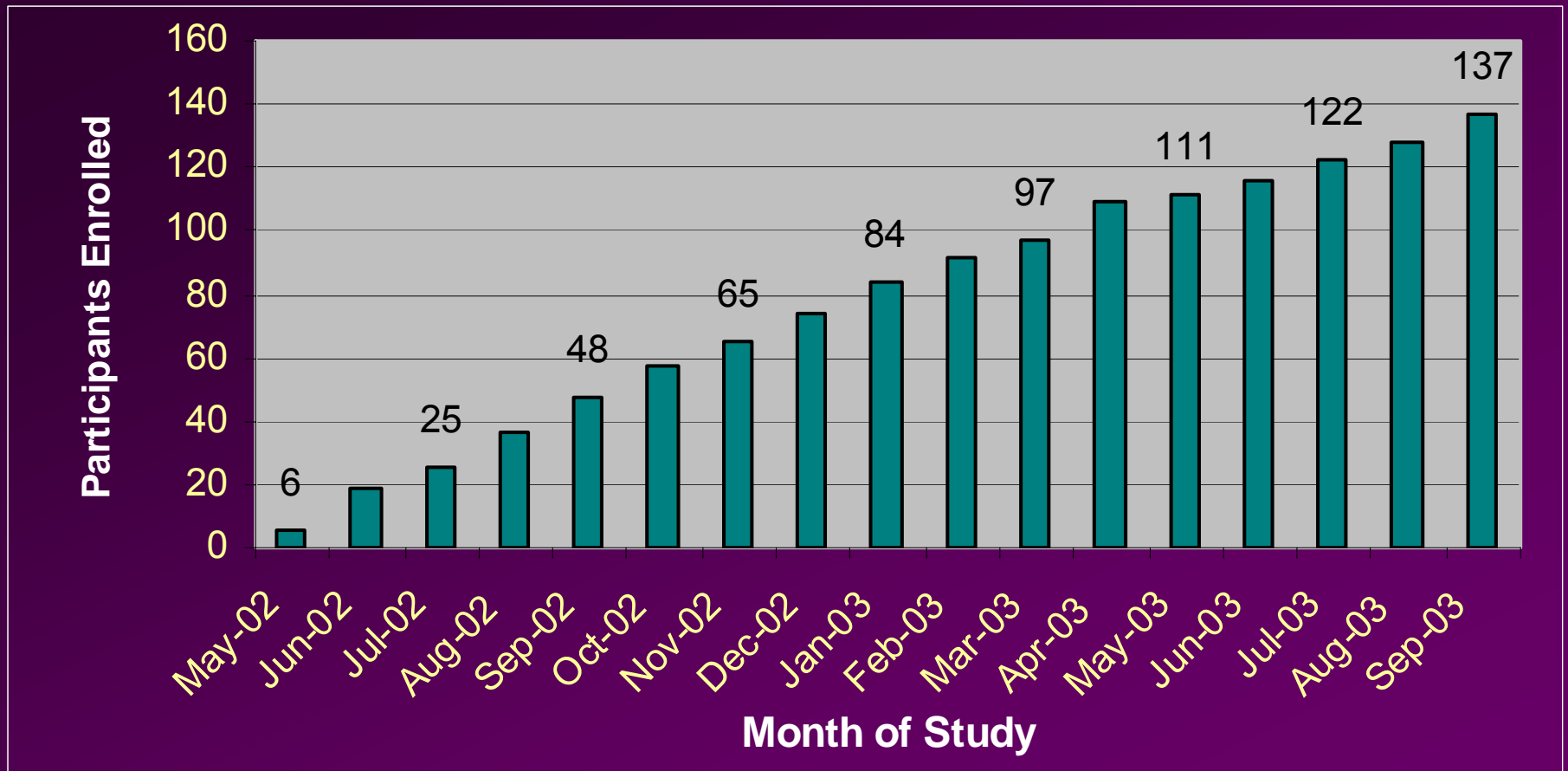




# MEMS

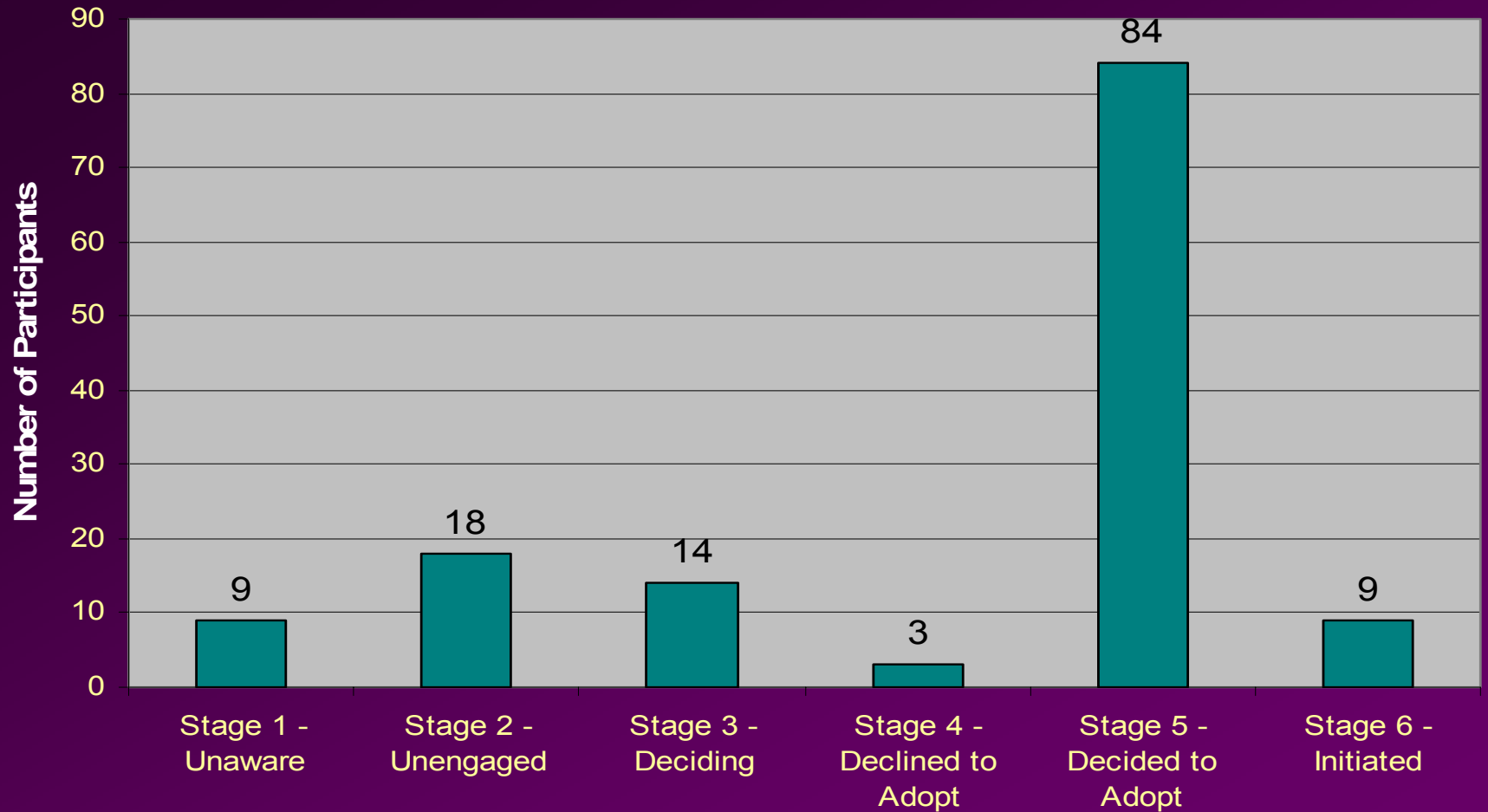


# Study Recruitment



**Average Monthly Recruitment: 8.06 pts**

# Participant Distribution by Stage



# Patient Characteristics

	(n=137)
<b>Gender (%)</b>	
Women	29.9
<b>Age (yrs)</b>	
Mean age	38.3
Age range	18-90
<b>Race/Ethnicity (%)</b>	
African	33.6
African-American	44.5
Latino	10.2
Other	11.6

# Patient Characteristics

	(n=137) %
<b>Married *</b>	35.0
<b>Foreign Born</b>	58.3
<b>Homelessness</b>	
Ever Homeless	35.8
Currently Homeless	14.6
Currently in Shelter	16.8

\* Includes “living together as married”

# Summary

- The study enrolled a diverse population of patients with LTBI
- A significant proportion of patients were foreign-born and many were homeless
- PAPM questionnaire identified various stages of readiness regarding LTBI treatment

# Challenges

- Population
- Declining to adopt
- Retention
- Measurement issues

# TAPAS Team

## Staff/Peers

- Nancy Holson, MPH
- Rita Sondengam, MPH
- Maggie Whelan
- Jenelle Norin
- Sherry Pettaway
- Michael Holcomb
- Eugene Smith
- Ibrahima Cisse
- Lydia Mercado

## Investigators

- Wafaa El-Sadr, MD, MPH
- Paul Colson, PhD
- Bill Bower, MPH
- Beverly Diamond, DSW
- Julie Franks, PhD
- Yael Hirsch-Moverman, MPH
- Sharon Mannheimer, MD
- Sherry Glied, PhD